Patent Docket P1129R1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Avi J. Ashkenazi et al. Serial No.: 09/114,844 Filed: 14 July 1998 For: RTD RECEPTOR	Group Art Unit: 1646 Examiner: C. Kaufman

RESPONSE/REMARKS

Sir:

This paper is being filed concurrently with Applicants' Request for Continued Examination (RCE). Consideration of the remarks herein is respectfully requested.

Claims 1-14, 29, 34, 35, and 38-58 are pending.

Claims 1-6, 8-14, 29, 38-45, 47-55, 57 and 58 were previously rejected under Section 102(e) as being anticipated by Ni et al., US Patent 6,124,580.

In our previously filed Responses, Applicants provided the Examiner a detailed analysis of the Ni et al. priority applications. Briefly, Ni et al. claim priority to two different provisional applications - the first priority application of Ni et al. was filed before the August 26, 1997 priority filing date of the instant application while Ni et al.'s second priority application was filed after the August 26, 1997 priority filing date of the instant application.

The Ni et al. patent discloses a polypeptide, referred to as TR10, encoded by a cDNA cloned from a cDNA library. While the first priority application of Ni et al. discloses the cDNA sequence and deduced amino acid sequence of TR10, it fails to teach or suggest to one skilled in the art how to make and use the TR10 molecule. Example 4 in the Ni et al. first priority application (see pages 59-61 of first priority application) describes experimental results of certain Northern blot assays, but the data from those assays (e.g. that mRNA expression was

found in multiple human normal and cancer cells and tissues) clearly does not provide sufficient disclosure as to the function of TR10. All of the remaining "examples" in the first priority application of Ni et al. are indeed prophetic, as can be seen from the fact that the examples are expressed throughout in the present tense.

The function, utility, and binding property(s) of the TR10 were solely postulated in the Ni et al. first priority application, based on sequence homology between the sequences of TR10 and other TNF receptor family members. Contrary to the Examiner's assertion, Ni et al. do NOT show binding of TR10 to Apo-2 ligand; that, too, is simply another prophetic guess on the part of Ni et al. As explained below, simply "guessing" in this receptor technology is not sufficient guidance to one skilled in the art. While as the Examiner notes in the Office Action that the Patent Laws do not mandate experimental testing, a prophetic teaching is only permitted where there is a reasonable expectation or reasonable prediction that the invention may be made and used in the way set forth by an Applicant. This receptor technology field is not reasonably predictable (absent any experimental characterization), and so a mere hypothesis on the part of Ni et al. does not suffice.

The TR10 molecule was not actually expressed or tested by Ni et al., and therefore its function or utility was not experimentally determined. In particular, Applicants wish to point out at least two factors why Ni et al. were <u>not</u> in a position to postulate function or utility of TR10 at the time of filing their first priority application. First, Ni et al. themselves teach in their specification that the "effects of TNF family ligands and receptors are varied and influence numerous functions, both normal and abnormal, in the biological processes of the mammalian system." (First priority application at page 5, lines 6-8; see also, page 34, lines 4-25). Such teachings clearly indicate that Ni et al. could not have reasonably predicted what function or activity TR10 may or may not have. Second, it is important to note the prophetic Example 5 provided on pages 62-63 of the first priority application. Example 5 teaches that TR10 will exhibit apoptotic activity. This speculative teaching is clearly wrong, as taught by Applicants' instant application, and by Ni et al.'s later filed application (as noted below).

The Ni et al. second priority application was filed December 9, 1997, which is after the August 26, 1997 priority filing date of the instant application. It was not until the second priority application that Ni et al. experimentally found that TR10 bound Apo-2 ligand or inhibited apoptotic activity by Apo-2 ligand. As noted above, this finding is completely opposite of that reported by Ni et al. in Example 5 of the first priority application.[1] Accordingly, the Ni et al. patent is not entitled to its May 30, 1997 priority filing date for purposes of Section 102(e) against the instant claims.

Applicants invite the Examiner to review the decision of the Board of Patent Appeals and Interferences in Interference No. 104,002 involving US Application Serial No. 08/479,620 and US Application No. 08/464,594. In that decision the Board considered similar facts, wherein a party had identified a sequence from a cDNA library, and through sequence comparisons, found sequence structure similarity between the novel sequence being claimed and other known molecules belonging to the chemokine family. The Board found that in view of the pleiotropic nature of the many activities or functions attributed to the family of chemokine molecules, simply identifying sequence similarity or homology to other known chemokines does not establish a specific practical utility for the novel molecule nor does it reveal how such a novel molecule might work.

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[1]Compare the titles of Example 5 in the first priority application at page 62, "TR10 Induced Apoptosis", and that of Example 5 in the second priority application at page 41, "TR10 Inhibits TRAIL Induced Apoptosis."

Applicants submit for the reasons presented above, and in view of the Board's reasoning in the Interference No. 104,002 decision, that the Ni et al. patent cannot be properly cited against the present application under Section 102(e).

Respectfully submitted,
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RCE

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May 6, 2005

Diane L Marschang

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TRANSMITTAL LETTER

Mail Stop RCE
Commissioner for Patents
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Sir:

Transmitted herewith are the following documents:

1. Request for Continued Examination (RCE) (dup);
2. Petition and Fee for Extension of Time (dup);
3. Response;
4. Return postcard.

In the event any additional fees are due in connection with the filing of these documents, the Commissioner is authorized to charge such fees to our Deposit Account No. 07-0630.

Respectfully submitted,

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